

REMARKS

The claims are 18 to 29. Claim 18 has been amended to further define the present invention. Claim 30 has been cancelled without prejudice. Reconsideration of the present claims is respectfully requested.

Claim 18 has been amended to make clear that the method is directed to a pullulan containing film. Support for the amendment can be found at page 10, line 2 of the specification and claims as originally filed. Therefore, these changes are not new matter.

Rejection under 35 USC §103

Claims 18-30 were rejected under 35 U.S.C. § 102 (b) as being allegedly unpatentable over U.S. Patent No. 5,948,430 to Zerbe et al. ("Zerbe") or U.S. Patent No. 5,629,003 to Horstmann et al. ("Horstmann") in view of WO 98/11867 to Nair et al. (Nair) and in further view of in view of U.S. Patent No. 4,562,020 to Hijiya et al. ("Hijiya").

? NO
comb.

Applicants, respectfully, traverse this rejection.

Zerbe is directed to a water soluble polymer film that rapidly softens and completely disintegrates in the oral environment. The film includes at least one cosmetic or pharmaceutical ingredient. While menthol is mentioned as a cosmetically active flavor for breath freshening, Zerbe nowhere teaches or suggests combining *at least two* essential oils for antimicrobial efficacy in a pullulan containing film. Accordingly, it is respectfully submitted that the claims would not have been obvious over Zerbe.

Horstmann discloses a sheet-like, individually dosed presentation, which is in the form of a film, that rapidly disintegrates in water, and a process for the production of such a presentation. The presentation comprises a mass consisting of 20 to 60 % by weight of at least one film-forming agent, 2 to 40 % of at least one get forming agent, 0.1 to 35 % of at least one active substance, and up to 40 % of at least one inert filling agent.

Processing of the presentation may be conducted according to a process known in the art.

Column 4, lines 19 to 52.

Horstmann, however, nowhere discloses or suggests a pullulan containing film comprising a mixture containing an effective antimicrobial amount of at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, let alone a method for preparing such a film. Peppermint oil is disclosed apparently as a flavor – antimicrobial properties are nowhere mentioned. Accordingly, it is respectfully submitted that the claims would not have been obvious over Horstmann.

Moreover, the deficiencies of Zerbe and Horstman are not remedied by the disclosure of Nair. As noted by the Examiner, Nair does describe the use of the essential oils thymol, eucalyptol, menthol and methyl salicylate in oral composition for antimicrobial purposes. Importantly, however, the oral compositions described in Nair are “fluid” type dosage forms (mouthwashes or mouth rinses and dentifrices), compositions generally requiring mechanical influence (swishing or brushing) for efficacy. In contrast, the film compositions of the present invention are “solid” dosage forms requiring no mechanical influence for efficacy. Moreover, not only is the delivery device provided by the present invention significantly different than that suggested by Nair, but so is the antimicrobial efficacy of the essential oils delivered thereby. Specifically - and without being limited by theory, the present inventors believe that the solid film of the present invention aids in sustaining the antimicrobial efficacy of the product by forming a thin layer on the oral surface which “entraps” the essential oils – *undisturbed by swishing and/or brushing*. Recognizing these distinctions, it is respectfully submitted that one of ordinary skill in the art would not have arrived, nor had a reasonable expectation of

arriving, at the film compositions of the present invention based on a combination of either Zerbe or Horstman with Nair.

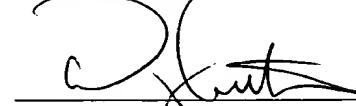
Similarly Hijiya does nothing to overcome the deficiencies of Zerby, Horstmann, and Nair. Hijiya discloses a continuous process for producing a self-supporting, water-soluble, glucan film. Menthol is disclosed as a cosmetically active agent. Hijiya, however, nowhere teaches or suggests a method comprising the step of mixing oils to form an oil mixture comprising an antimicrobially effective amount of at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol. Therefore, even if the disclosure of Hijiya is combined with Nair and either Horstmann or Zerbe, the resulting combinations would not teach or suggest the claimed method for arriving at the antimicrobially active compositions of the present invention.

Therefore, since neither Zerby, Horstmann, Nair, nor Hijiya, singly or in combination, teach or suggest the presently claimed method, it is respectfully submitted that the present claims would not have been obvious over these references.

Accordingly, it is respectfully requested that the claims be allowed and the case be passed to issue.

Applicants' undersigned attorney may be reached by telephone at (973) 385-4401. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


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VERSION MARKED TO SHOW CLAIM CHANGES

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18. (amended) A method for preparing a physiologically compatible film that adheres to and dissolves in a consumer's mouth said method comprising:

mixing [at least one water soluble film former] pullulan and at least one stabilizing agent to provide a film-forming mixture;

dissolving water-soluble ingredients in water to provide an aqueous solution;

combining said film forming mixture and said aqueous solution to provide a hydrated polymer gel;

mixing oils to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol;

adding said oil mixture to said hydrated polymer gel and mixing to provide a uniform gel;

casting the uniform gel on a substrate; and

drying the cast gel to provide said film that adheres to and dissolves in a consumer's mouth.